



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (External Preparation)	<b>SOP No.:</b>
<b>Title:</b> Cleaning, Sanitization & Operation of Multi Mix Plant with Load Cell 250 Kg	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a Procedure for Cleaning, Sanitization & Operation of Multi Mix Plant with Load Cell 250 kg.

### 2.0 SCOPE:

This SOP is applicable for Cleaning, Sanitization & Operation of Multi Mix Plant with Load Cell 250 kg.

### 3.0 RESPONSIBILITY:

Operating Person: Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
&	And
PO	Production Ointment
Kg	Kilogram
Pvt.	Private
Ltd.	Limited
°C	Degree centigrade
Min.	Minute
%	Percentage
v/v	volume/volume
Hrs.	Hours
Kg/cm <sup>2</sup>	Kilogram per square centimeter

### 6.0 PROCEDURE:

#### 6.1 Cleaning:

##### 6.1.1 A Type Cleaning (Batch to Batch & Shift End Cleaning):

**6.1.1.1** Ensure that the equipment has a "TO BE CLEANED" Status Label.

**6.1.1.2** Check for any previous product residue and remove the adhered residue/lump of previous product (if available on paddle/shaft of stirrer) by manual scrubbing with long handled Teflon scrapper or purified water.

**6.1.1.3** Take the 150 kg Purified Water in Multi-Mixer and heat up to 75°C to 80°C under stirring then start the Homogenizer for 05 Min.



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**6.1.1.4** Now open the Drainage Valve and Drain the Hot Purified Water with the help of Transfer Pump.

**6.1.1.5** Finally rinse the multi mixture plant with purified water by passing the purified water and recirculate the water through product pipe line and lobe pump and drain out the purified water through discharge valve.

**6.1.1.6** Dry mop the outer surface of Multi-Mixer with Lint Free Cloth.

**6.1.1.7** Affix a “CLEANED” Status Label on the Vessel.

**6.1.1.8** Make an entry of Cleaning Time in Equipment Log as per reference SOP.

**6.1.1.9 A - Type Cleaning is to be done**

1. Batch to Batch changeover of the same product.
2. Change over to higher strength of same colour.

**6.1.2 B Type Cleaning (Product to Product Cleaning)**

**6.1.2.1** Ensure that the Equipment has a “TO BE CLEANED” Status Label on it.

**6.1.2.2** Check for any previous product residue and remove the adhered residue/lump of previous product (if available on paddle/shaft of stirrer) by manual scrubbing with long handled Teflon scrapper or purified water.

**6.1.2.3** Take the 200 kg Purified Water in Multi-Mixer plant and apply steam 1kg/cm<sup>2</sup> till its heated up to 75°C to 80°C under stirring then start the Homogenizer for 05 Minutes and recirculate the water through product pipe line.

**6.1.2.4** Now open the Drainage Valve and Drain the Hot Purified Water with the help of Transfer Pump.

**6.1.2.5** If previous product residues are not remove (visual check) then repeat process of point no. **6.1.2.3 & 6.1.2.4.**

**6.1.2.6** Manually pour/Sprinkle 4-5 liters Extran MA 02 solution 2% v/v into inner surface of the multi mix plant and recirculate the Extran solution into the product pipe line and lobe pump and drain out.

**6.1.2.7** Final rinse the vessels with approx. 200 liter of hot purified water and recirculate the water through to product pipe line and lobe pump for remove the Extran traces from the pipeline & vessel and drain out the purified water.

**6.1.2.8** Dismantle all parts of Multi-Mixer for cleaning.

**6.1.2.9** Wrap the dismantle parts and then transferred to the wash area for cleaning.

**6.1.2.10** Clean the parts with Hot Purified Water and dry them with Compressed Air.

**6.1.2.11** Collect the cleaned & dry parts and assemble them with multimixer plant.



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**6.1.2.12** Again Wash and flush the Multi-Mixer with Purified Water.

**6.1.2.13** Ensure the cleanliness of Vessel visually, if not cleaned properly then repeat the process from point no. **6.1.2.6 to 6.1.2.12.**

**6.1.2.14** Make an entry of Cleaning Time in Equipment Log. In **Reference SOP.**

**6.1.2.15 B-Type Cleaning is to be done**

1. After 48 hrs. of type A-Type cleaning.
2. Product Change Over.
3. Change over to Lower strength of same product.
4. After maintenance or major breakdown.
5. Change over to upper strength with different colour.
6. If the Equipment is not used within 72 hours clean the equipment before use.
7. After every 5 batches of same product in case of campaign product.

### **6.2 Hot Water Sanitization:**

**6.2.1** Take 100 Liter Purified Water into wax and water phase vessel & Heat up to 80°C to 85°C and transfer into main mixing vessel through vacuum & run slow speed stirrer and recirculation of hot purified water for 15 Minutes.

**6.2.2** Now open the Drainage Valve and Drain the Hot Purified Water with the help of Transfer Pump.

**6.2.3** Dry the inner surface of Multi-Mixer plant with steam for approx. 2 minutes.

**6.2.4** Dry mop the outer surface of Multi-Mixer with Lint Free Cloth.

**6.2.5** Affix the “**CLEANED**” Status Label on the Multi Mixer.

**6.2.6** Make an entry in Multimixer plant with load cell sanitation record as per Annexure -1 of SOP “Cleaning, Sanitization & Operation of Multi Mix Plant with Load Cell”

**6.2.7** Send the Rinse Sample to QC for Testing.

**6.2.8** If Testing Results not complies with Reference Specification, again follow steps no.**6.2.1 to 6.2.7.**

**Frequency: After B Type Cleaning**

### **6.3 Operation:**



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### 6.3.1 Programmable Logic Control (PLC) Operation System for Load Cell :

#### 6.3.1.1 Display Operation:

When in the weighing mode, the display is used for indicating the weight value and other types of information related to the weight. The other information provided includes:

- **Weight unit (lb, kg, g, ton, t)**
- **Motion / No-motion condition**
- **Center of zero**
- **Gross or net mode**



When accessing the operator menu or setup mode, the display is also used to display icons, parameters and settings.



### 6.4 KEYPAD OPERATION:



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**ZERO:** When the scale platform or weighbridge is empty, the terminal should indicate zero. The gross zero reference is recorded during calibration. Press the ZERO scale function key to capture a new gross zero reference point if pushbutton zero is enabled in configuration and the weight is within the zero range.



**TARE:** Tare is the weight of an empty container. The tare weight is can be subtracted from the gross weight of a package to determine the net weight of the contents of a container. Press the TARE key when an empty container is on the scale. The terminal then displays a zero net weight. As the container is loaded, the terminal then displays the net weight of the contents. Pushbutton tare must be enabled to use the Tare key.



**CLEAR:** When in the net weight mode, if the Clear key is pressed, the current tare value will be cleared which will cause the weight display to revert to the gross weight value. The Clear key operates regardless of motion on the scale. Note that once the tare value has been cleared, it cannot be recalled. The complete tare process as described above must be performed.



**PRINT:** Press the PRINT scale function key to initiate a demand output of the programmed print data. A demand output connection must be configured for the selected serial port. This key also provides The Zero, Tare and Print functions will not operate when there is motion on the scale. If one of these keys is pressed while the scale is in motion, the command will be retained for 3 seconds while the terminal waits for no-motion. If a no-motion condition is not detected within the 3 seconds, the request is cancelled and discarded.

### 6.5 Operator Menu:



**Target:** Access to all target values including the target, tolerances, fine feed and spill values.



**Comparators:**

Access to the limit value (and high limit value if the comparator is programmed as a range) for all comparators.



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**Information:** Recall mode for all terminal information fields.



**Calibration:** Quick access to zero and span adjustment (in non-approved mode only).



**Setup:** Access to all setup parameters for the terminal.

### Data Entry:

1. Press ID key to enter alphabetical & numerical data.
2. Batch Name will show on display.
3. Type Batch Name by pressing keys followed by alphabets shown on display.
4. Press ENTER key to SAVE Batch Name.
5. Now, Batch Number will be shown on display.
6. Type Batch Number by pressing keys followed by alphabets shown on display.
7. Press ENTER key to SAVE Batch Number.
8. Now, Net Weight of Batch will show on display.
9. Press Printout key for output programmed print data.

### 7.0 ANNEXURES:

Not Applicable.

### 8.0 DISTRIBUTION:

- Controlled Copy No. 01                      Quality Assurance
- Controlled Copy No. 02                      Production
- Master Copy                                      Quality Assurance

### 9.0 REFERENCES:

Not Applicable.

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By